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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,650	07/07/2003	Yong Hua Zhu	LOMAU.122C1	7638

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EXAMINER

HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/614,650	Applicant(s) ZHU ET AL.	
	Examiner MELANIE J. HAND	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4,6,8-15,17-22 and 24-41 is/are pending in the application.
- 4a) Of the above claim(s) 2-4,8,9,11-15,17-20 and 25-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,21,22,24,34-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/29/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 10, 21, 22, 24, 34 and 35 have been considered but are moot in view of the new ground(s) of rejection prompted by applicant's amendment to the claims.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on May 29, 2008 was filed after the mailing date of the non-final action on November 8, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 10, 21, 22, 2, 34-36 and 38-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Barak (U.S. Patent No. 6,048,358).

With respect to **claim 21**: Barak teaches a device for at least partially closing an opening in an artery comprising an elongate body in the form of catheter introducer 10 comprising a first

lumen 14 having a first distal opening at forward end 21 and a second lumen 22 having a second distal opening (Figs. 1A,B). The first and second lumens 14,22 are arranged so that a longitudinal space is defined between the first and second distal openings. A first connector in the form of catheter head 16 is adapted to provide access to the first lumen 14. A second connector defined by the body of valve assembly 24 is adapted to provide access for a syringe 66 to the second lumen 22 to inflate balloon 20. A wound cover member in the form of anchor balloon 48 is releasably connected to the body at the first distal opening of lumen 14 inasmuch as the balloon 48 initially abuts end 21 of lumen 14, i.e. the distal opening, thus being connected, and subsequently enables a sealing arrangement that causes homeostasis to occur to close the puncture, and the anchor balloon 48 and anchor assembly 44 are removed. Examiner's position regarding the balloon as wound cover is based upon Barak's teaching that the balloon both seals a puncture in the instant artery, i.e. the wound, and covers the wound on the inside surface 72 of the artery (see Fig. 9). The balloon lumen 22 is formed integrally as part of introducer 10 and lumen 14 and thus the first distal opening of first lumen 14 is permanently maintained at a position distal of the second distal opening of second lumen 22, and the first and second lumens do not communicate with one another.

With regard to the limitation "for at least partially closing an opening in tissue", since the device of Barak meets all of the claim limitations as to a catheter and wound cover, and is intended to close openings in an artery, the device of Barak is fully capable of functioning as a device for at least partially closing an opening in tissue and thus anticipates the limitation of a device for at least partially closing an opening in tissue.

With respect to **claim 10**: The elongate body 10 has a first portion comprising the first lumen 14 and a second portion at the distal end of body 21 comprising the second lumen 22. The lumen

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22 is formed at the distal end 21 of body 10 and thus first and second portions are rigidly connected to one another so as to always move as a single elongate unit. (Col. 4, lines 49-55, 58-62)

With respect to **claim 22**: The second lumen 22 is an inflation lumen for balloon 20 and is thus configured to communicate a flowing fluid, namely pressurized inflation fluid, therethrough. (Col. 4, lines 58-65)

With respect to **claim 24**: The device additionally comprises a release rod in the form of anchor assembly 44 having sheath 46 sized and configured to slide through the first lumen 14 and into contact with the wound cover member 48 inasmuch as the balloon 48 is formed at the end of sheath 46 and is already in contact with the wound cover member, thus it is configured to come into contact with said wound cover member 48. (Fig. 8, Col. 5, lines 21-26)

With respect to **claim 34**: The device of Barak additionally comprises a release rod in the form of sheath 46 of anchor assembly 44, wherein the first lumen 14 is concentric with, and larger in diameter than, rod 46 and is thus necessarily adapted to slidably receive the release rod 46 therein. (Fig. 8)

With respect to **claim 35**: The wound cover member 48, i.e. the balloon 48 in its inflated state, has a maximum diameter that is greater than a diameter of the second lumen distal opening. (Figs 1A-B, 8)

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With respect to **claim 36**: The first connector is a catheter head 16 for receiving a catheter, which can be a source of vacuum. Thus the first connector 16 is adapted to connect to a source of vacuum so as to draw a vacuum through the first lumen 14.

With respect to **claim 38**: The second connector 24 is adapted to selectively connect to a source of vacuum inasmuch as Barak teaches that it can selectively connect to a syringe, wherein syringes by their nature are fully capable of drawing vacuum through the second lumen by pulling the plunger back away from the second connector, thus anticipating the limitation “adapted to selectively connect to a source of vacuum so as to draw a vacuum through the second lumen”.

With respect to **claim 39**: The second connector 24 is adapted to selectively connect to a source of irrigation fluid, namely syringe 66. (Col. 5, lines 46-48)

With respect to **claim 40**: The second connector is adapted to selectively connect to a source of flowable adhesive inasmuch as Barak teaches that the second connector 24 is selectively connected to a syringe which is fully capable of functioning as a source of adhesive. With regard to the limitation “so that flowable adhesive may flow through the second lumen and out the second distal opening”, though Barak teaches that the second lumen 22 is an inflation lumen, the lumen is perfectly capable of transporting flowable adhesive from the connector 24 and the syringe to the second lumen and second lumen distal opening and thus the prior art of Barak anticipates this limitation.

With respect to **claim 41**: The second connector 24 defines a second connector lumen for inflation fluid to flow through, and an axis of the second connector lumen is disposed in a direction generally transverse to an axis of the second lumen 22, whose axis is parallel to the axis of the first lumen 14. (Fig. 1A, Col. 5, lines 46-48)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barak ('358).

With respect to **claim 37**: The wound closure member 48 taught by Barak is held onto the first lumen distal opening by its attachment to rod 46. Since the balloon abuts the distal end 21 of lumen 14, the wound closure member is fully capable of being held onto the first lumen distal opening by vacuum.

Barak teaches that the wound cover member 48 abuts or is connected to the distal opening at end 21, but does not explicitly teach holding the wound cover member onto the first lumen distal opening by vacuum. However, holding via vacuum is simply an alternate means of securing the wound cover member 48 to the distal opening that accomplished the identical result of connecting or abutting the wound cover member to the distal end 21 as taught by Barak. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Barak such that the wound cover member 48 is held onto the first lumen distal opening by vacuum with a reasonable expectation of success.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761